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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,042	12/11/2003	Markley C. Leavitt	AVI-028	9363

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EXAMINER	
WILSON, MICHAEL C	
ART UNIT	**PAPER NUMBER**
1632	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/733,042	LEAVITT ET AL.	
	Examiner	Art Unit	
	Michael C. Wilson	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-70* is/are pending in the application.

4a) Of the above claim(s) *42-70* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3-8-04&6-26-04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-41 in the reply filed on 1-22-07 is acknowledged.

Claims 42-70 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 1-22-07.

Claims 1-41 are under consideration.

Specification

The status of the applications throughout the specification will need to be updated upon being allowed, e.g. pg 43, line 24.

"Figure b" on pg 43, line 23, does not exist.

"The present invention provides a novel isolated nucleic acid molecule of approximately 195 kb of the chicken genome, and truncated variants thereof, comprising a region of about 135 kb that is 5' upstream, and an approximately 45 kb region that is 3' downstream, of the ovalbumin-encoding region of the gene locus" (pg 5, lines 5-9).

BAC 120 is nucleotides 1-157354 of SEQ ID NO: 1. BAC 77 is 157355-195102 of SEQ ID NO: 1. The nucleic acid sequence of the chicken genomic region SEQ ID NO: 1 is shown in Fig. 1 (pg 20, lines 13-27). Thus, it appears that SEQ ID NO: 1

encodes BAC vector as well as the entire genomic sequence of the ovalbumin gene and matrix attachment regions.

cDNA encoding an immunoglobulin or luciferase was inserted into ~195 kb ovalbumin BAC (pg 43, lines 12-21; pg 44, lines 7-14).

Claim Rejections - 35 USC § 112

Indefiniteness

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3 and 27-28 are indefinite because the structural features that define chicken matrix attachment regions (MAR) vary and are not defined in the specification or known in the art. Pg 3, lines 20, states, "[a]lthough MAR nucleic acid sequences are conserved, little cross-hybridization is seen, indicating significant overall sequence variation." In addition, a MAR from one species can interact with other species (lines 22-30). Therefore, it cannot be determined when a sequence is a MAR, specifically a chicken MAR. The specification states individual cis-transcriptional regulatory elements associated with the chicken ovalbumin gene have been isolated together (pg 4, lines 11-13). However, those of skill cannot determine whether fragments known in the art comprised an ovalbumin promoter and a MAR. For example, Woo (1978 cited below)

taught 1.8, 2.4 and 9.5 kb fragments of the ovalbumin gene; however, those of skill could not reasonably establish whether the fragments comprise MAR. Accordingly, those of skill could not reasonably know when a sequence comprised a MAR, specifically when an ovalbumin gene fragment comprising the ovalbumin promoter also comprised a chicken MAR as claimed.

Claim 10 is indefinite because it is unclear if the claim encompasses variants of the "at least 103 kb of SEQ ID NO: 1" or if the claim is limited to a nucleic acid that is truncation of SEQ ID NO: 1 that comprises at least 103 kb. The phrase "truncated variant" makes the claim unclear.

Claim 11 is indefinite because it is unclear if the claim encompasses variants of the fragments of SEQ ID NO: 1 or if the claim is limited to a nucleic acid that is a truncation of SEQ ID NO: 1 that consists of about position 41000, 56000, 58350, 76200 or 80000 to about 191500, 187000, 164500, 157600, 157100, 15200 or 145500 of SEQ ID NO: 1. The phrase "truncated variant" makes the claim unclear.

Likewise, claims 12-22 are indefinite because "truncated variant" makes the claims unclear.

The phrase "A vector inserted therein" in claim 23 and 34 does not make sense.

Claim 25 should refer to "the nucleic acid molecule according to claim 1."

Claim 27 is indefinite because the phrase "independently capable of hybridizing under high stringency conditions to the nucleic acid sequence according to SEQ ID NO: 1" is unclear. The metes and bounds of "independently capable" are unclear. It cannot

be determine whether the sequence of claim 1 or fragments of the sequence of claim 1 must hybridize to SEQ ID NO: 1.

Likewise, claim 28 is indefinite because "independently capable" is unclear. The claim does not clearly set forth the structure of the nucleic acid sequence or the functional fragment of the sequence of claim 1 that must hybridize to SEQ ID NO: 1.

The metes and bounds of a heterologous nucleic acid sequence in claim 29 are unclear. It cannot be determined when a nucleic acid is heterologous as claimed. For example, SEQ ID NO: 1 comprises numerous fragments that are heterologous to the ovalbumin promoter, but it cannot be determined if these fragments are included or excluded from the claim.

The metes and bounds of an endogenous nucleic acid sequence in claim 30 are similarly unclear. It cannot be determined when a nucleic acid is endogenous as claimed, i.e. to a chicken, to the ovalbumin gene, to SEQ ID NO: 1; therefore, the scope of the claim cannot be determined.

The metes and bounds of what applicants consider "tissue-specific expression" cannot be determined in claim 31. The phrase does not have an art-accepted meaning and is not defined in the specification.

The use of a "second heterologous sequence" in claim 33 does not make sense because the nucleic acid sequence does not have a first heterologous sequence and because "heterologous" is relative. It cannot be determined when a nucleic acid is heterologous as claimed.

The metes and bounds of when a "sequence encodes a polypeptide having a codon complement optimized for protein expression" in claim 37 cannot be determined. It cannot be determined what is being optimized or what is optimal.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The 195,102 bp of SEQ ID NO: 1 cannot be reasonably searched because of its large size. In fact, the smallest sequence claimed is a 65,000 bp fragment in claim 11

(from about position 80,000 to about 145,500), which also cannot be reasonably searched because of its large size. Accordingly, the art rejections are based on searches of fragments of SEQ ID NO: 1 and what was known in the art at the time of filing.

Claims 1-4, 23, 24, 26-31, 34-37 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Woo (PNAS, Aug. 1978, Vol. 75, No. 8, pg 3688-3692).

Woo taught cloning a 2.4, 1.8 and 9.5 kb fragment of the chicken ovalbumin gene using bacterial artificial chromosome vectors (pg 3688, col. 2, Bacteria and phages; pg 3689, col. 2, "Cloning of 2.4 kb ovalbumin DNA fragment"; pg 3690, col. 2, first line of "Biological characterization of "insert sequences"). The 2.4 and 1.8 kb fragments are comprised of about 0.45 and 0.30 kb of structural ovalbumin gene sequences and 1.95 and 1.50 kb of intervening sequences (pg 3690, col. 2, second line of "Biological characterization of "insert sequences"). "Expression of the intervening sequences is induced by steroid hormones in a coordinate manner with the structural ovalbumin gene sequences" (pg 3691, col. 1, last sentence of first partial paragraph).

The structure of matrix attachment regions (MAR) varies, and the Patent office does not have the ability to determine whether the nucleic acid sequence described by Schreiber comprises MAR. Accordingly, without evidence to the contrary, the sequence disclosed by Schreiber comprises at least two avian matrix attachment regions (MAR) because it comprises the 5' and 3' non-coding regions of the ovalbumin gene. In addition, one of the artificial chromosomes (BAC) comprising the ovalbumin gene has a MAR and the ovalbumin promoter as in claims 23 and 24. The sequence is

"recombinant" as in claim 26 because it was processed in vitro. The MAR and promoter in the sequence of Schreiber would hybridize to portions of SEQ ID NO: 1 as in claims 27 and 28. Claim 29 is included because the metes and bounds of "heterologous nucleic acid sequence" cannot be determined. Claim 30 is included because the endogenous coding region of ovalbumin is linked to the ovalbumin promoter. Claim 31 is included because the ovalbumin promoter within the sequence of Schreiber has the same structure and, therefore, is "capable of tissue-specific transcription" as claimed. Claim 37 is included because the metes and bounds of "a codon complement optimized for protein expression in an avian" are unclear.

Claims 1-4, 23, 24, 26-31, 34-37 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Woo (Biochem., 1981, Vol. 20, pg 6437-6446).

Woo taught the complete nucleotide sequence of the chicken ovalbumin gene is 7564 bp (first 4 lines of abstract). The sequence was compiled after sequencing of numerous plasmids comprising various segments (paragraph bridging pg 6437-6446; pg 6438, Structure and sequencing of the complete gene). The structure of matrix attachment regions (MAR) varies, and the Patent office does not have the ability to determine whether the nucleic acid sequence described by Woo comprises sequences that function as MAR. Accordingly, without evidence to the contrary, the sequence disclosed by Woo comprises at least two avian matrix attachment regions (MAR) because it comprises the 5' and 3' non-coding regions of the ovalbumin gene. In addition, one of the plasmids comprising a fragment of the ovalbumin gene (pg 6438, "Structure and sequencing...") has a MAR and the ovalbumin promoter as in claims 23

and 24. The sequence is "recombinant" as in claim 26 because it was processed in vitro. The MAR and promoter in the sequence of Woo would hybridize to portions of SEQ ID NO: 1 as in claims 27 and 28. Claim 29 is included because the metes and bounds of "heterologous nucleic acid sequence" cannot be determined. Claim 30 is included because the endogenous coding region of ovalbumin is linked to the ovalbumin promoter. Claim 31 is included because the ovalbumin promoter within the sequence of Woo has the same structure and, therefore, is "capable of tissue-specific transcription" as claimed. Claim 37 is included because the metes and bounds of "a codon complement optimized for protein expression in an avian" are unclear.

Claims 1-7, 23, 24, 26-31, 34-37 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Schreiber (AC159826, submitted 2001).

Schreiber taught a BAC clone CH261-57J20, Accession Number: AC159826. The sequence was 207137 bp in length. Without evidence to the contrary, the sequence disclosed by Schreiber comprises SEQ ID NO: 1. The structure of matrix attachment regions (MAR) varies, and the Patent office does not have the ability to determine whether the nucleic acid sequence described by Schreiber comprises MAR. Accordingly, without evidence to the contrary, the sequence disclosed by Schreiber comprises at least two avian matrix attachment regions (MAR) because it comprises the 5' and 3' non-coding regions of the ovalbumin gene. In addition, one of the artificial chromosomes (BAC) comprising the ovalbumin gene has a MAR and the ovalbumin promoter as in claims 23 and 24. The sequence is "recombinant" as in claim 26 because it was processed in vitro. The MAR and promoter in the sequence of

Schreiber would hybridize to portions of SEQ ID NO: 1 as in claims 27 and 28. Claim 29 is included because the metes and bounds of "heterologous nucleic acid sequence" cannot be determined. Claim 30 is included because the endogenous coding region of ovalbumin is linked to the ovalbumin promoter. Claim 31 is included because the ovalbumin promoter within the sequence of Schreiber has the same structure and, therefore, is "capable of tissue-specific transcription" as claimed. Claim 37 is included because the metes and bounds of "a codon complement optimized for protein expression in an avian" are unclear.

Conclusion

No claim is allowed.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached at the office on Monday, Tuesday, Thursday and Friday from 9:30 am to 6:00 pm at 571-272-0738.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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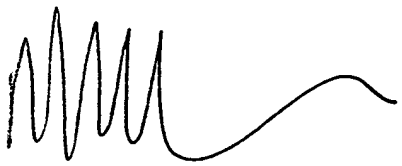
For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517.

The official fax number for this Group is (571) 273-8300.

Michael C. Wilson



MICHAEL WILSON
PRIMARY EXAMINER